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Dockets Management
Food and Drug Administration
5630 Fishers Lane Rm 1061
Rockville, Maryland 20852

Petition to restore FDA approval to Tecsana Epi-no birth trainer and to remove the adverse event report on Tecsana Epi-No from FDA website

Action requested: Restore FDA approval to Tecsana Epi-No birth trainer and remove adverse event report on Epi-No from your website

Grounds of the Petition: The grounds for my petition are based on my own research into the Epi-No, some of which I have published (**Cohain JS**. Perineal outcomes after practising with a perineal dilator.*MIDIRS Midwifery Digest* 2004;**14**(1):37–44.), and a case report submitted by Dr Linda M. Nicoll of NY Presbyterian Cornell Medical Center to OBGYN, the Journal of The American College of Obstetricians and Gynecologists (ACOG). It was authored by Dr Linda Nicoll and Dr Daniel W. Skupski. The case report was submitted for publication to the Obstetrics and Gynecology/ ACOG Journal Feb 2007. Following peer review, the case report was accepted for publication on the condition that the author answered the following 9 questions raised in the peer review process. The author did not and the article was not published.

1. Please include information about the infant's course after delivery.

2. Why would a chest x-ray be obtained after a chest CT?

3. Why would an MRI be obtained after a head CT?

4. Why was the patient continued on magnesium for 24 hours, given the likely diagnosis of air embolism and the unlikely diagnosis of eclampsia?

5. We hear only from the husband, paramedic and hospital staff. The mother's version of the events leading up to the hospitalization are needed.

6. If an air embolism was the cause, the authors do not establish how an air embolism entered the venus circulation. Was there an open vaginal gash that they failed to mention? How did air enter into the venous circulatory system, with membranes intact, the head of a 2.600 kilo baby engaged at 0 station, and

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almost no cervical dilation? There was no bleeding reported. No report of rupture of membranes. The authors fail to explain the mechanism of how 1.5 inches of a balloon, near the entrance to her vagina caused air embolism.

7. Why did the husband continue to attempt to insufflate the devise for ten to twenty minutes?

8. Why was an emergent cesarean delivery done if the presumed diagnosis was ecclampsia? Typically these patients are stabilized prior to delivery, not delivered emergently.

9. Why were cord gases not able to be obtained?

Certification Statement: I, Judy Slome Cohain, certify that to the best of my knowledge, this petition includes all information and views on which the petition relies and includes representative data and information known to the petitioner which are unfavorable to the petition.

Signed _____
Judy Slome Cohain

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Introduction:

This is a consumer complaint. I am an American trained Certified Nurse Midwife. I have no connection of any kind- financial or otherwise, to Tecsana. I don't sell Epi-No or represent the company in any way. I have nothing to gain from this petition except improving obstetric care and outcomes of obstetric care for women and their families, the same goals as I presume the FDA has. I am not being paid for writing this petition or any of my Epi-No research. I undertook an independent research project starting in 2000, to study the effectiveness of the Epi-No because I was skeptical of this new, expensive device which entered the market.

My research finds Epi-No to be effective and safe. Among 1,500 users in Israel, there have been 2 women (0.13%) who experienced perineal bleeding caused by practicing with the Epi-No that did not need suturing. Otherwise, the Epi-No is associated with about a 50% decrease in the episiotomy rate. 95% of the buyers of Epi-No were satisfied with their purchase, and this includes the 25% who still had an episiotomy despite using of the Epi-No.

The liberal use of episiotomy confounds the effect of the Epi-No. In a private midwifery practice in Israel, where episiotomy is never used, 189 consecutive primiparous women experienced a 28% rate of sutured tears. This is similar to

the 34% sutured tear rate that Albers reported in primiparous women. (Albers LL etal. Factors Related to Genital Tract Trauma in Normal Spontaneous Vaginal Births. Birth 2006. 33:2:94-100) In the same midwifery practice, among a group of 104 consecutive primipara women who practiced with Epi-No before birth, 10 (10%) experienced perineal tears. Neither group suffered from any third or fourth degree tears. This preliminary data is the first data to show the potential of Epi-No to prevent perineal damage even in an environment where women are not injured by episiotomy at birth. This 10% sutured perineal tear in the group of Epi-No users is the lowest reported perineal tear rate for primiparous women reported to date.

The most important thing to understand about the Epi-No is that it hurts to use it. It stretches the vagina to a circle with a 10 cm diameter, mimicking the size of the baby's head. Pain associated with the stretching of perineal tissues can be severe. (Niven C etal. Memory of labor pain: a review of the literature. Birth 2000. 27(4)244-53.) This means that only women who strongly want to prevent perineal damage are going to use it. It means that it is impossible to undertake a randomized controlled study of it, because the majority of women will not use it at all, or will say they used it but will not only inflate the balloon to about 6 cm, and not the 10 cm. point necessary for the perineum to subsequently act like the perineum of a woman who has already delivered a full term baby vaginally without tearing. Since 2006, the FDA has ordered that the Epi-no undergo rigorous randomized testing, but it is impossible to randomize a woman to a group in which she is supposed to undergo substantial pain caused by her own hand, for a purpose which may not interest her. She will only do so, if she believes it will pay off and if she is interested in the payoff. A woman who is highly interested in an intact perineum, to the point that she is willing to spend $120 and undergo rigorous painful exertion is very different from any control group in which women do not practice with Epi-No to 10 cm diameter. Although FDA is requiring such randomized testing, randomized controlled studies of the Epi-no are as impossible as randomly assigning women to climb Mt Everest and comparing them to a group that does not. Therefore the request that Epi-No undergo more randomized trials is an unrealistic request and reflects a lack of understanding for how the Epi-No works.

There are other devices like the JAS Joint Active System devices, a physical therapy device, which also require extreme motivation to use. For motivated people, it is an excellent system to return range of motion and muscle strength. But it cannot be studied in a randomized study, because many people do not have the personality type to undertake methodical and demanding protocols which do not have immediate results, typical of any diet or exercise regimen. The demand of randomized controlled studies of the Epi-no reflects a lack of familiarity with how it feels to use it. To someone like myself who is familiar with the device, and has helped women to use it, it is completely obvious that such demands are impossible to carry out. In addition, such randomized studies of even 1000 users will not add to the safety of the device. Enough people have used the Epi-no by now to know that blowing up a balloon in the vagina is not

dangerous. The silicone balloon is very sturdy and there is no risk of it popping in the vagina. There is no risk of air embolism because it is irrational and against the instructions to use an Epi-no with a hole in it. An Epi-no with a hole in it will not inflate, just as any balloon with a hole in it will not inflate. A balloon with a hole in it is impossible to inflate and therefore doesn't stretch anything- which is what the user is trying to do. Therefore, the only risk is tearing. This is possible, because the Epi-No puts pressure on the perineum, but it also pops out easily and is flexible, unlike the head of a baby, and cannot cause anything beyond a first degree tear when used according to instructions, and even that has only occurred at a rate of 1/700 users.

Although Epi-No is not for everybody, Epi-No is the only product that can deliver a decrease in perineal damage at birth. Until there is something else that can deliver this purpose, Epi-No needs to be made available as there is nothing else that can substitute to fulfill this purpose.

Epino birth trainer is the only option available for pregnant women, to decrease the risk of perineal tearing and episiotomy at the time of birth. It is the only effective tool available for this purpose. There are no other proven methods to use as a substitute for Epi-No to prevent perineal damage. Perineal massage has not been shown to be effective. (Beckmann MM, Garrett AJ. Antenatal perineal massage for reducing perineal trauma. Cochrane Database Syst Rev. 2006 Jan 25;(1):CD005123. Review.).

Epi-no has been held up to a level of scrutiny by the FDA that no other birth device has been held up to to-date. FDA approval was cancelled after an adverse event report in which someone used the Epi-No in an unapproved fashion. Fetal monitors, stirrups, episiotomy, forceps, vacuum, elective cesarean section, cytotec, pitocin, and antibiotics are all examples of frequently used birth routines, which if used in an unapproved fashion can cause damage or death to birthing women.

One adverse event was reported to the FDA website to have been associated with the use of the Epi-no birth trainer. In this case, there is absolutely no proof that an Epi-no birth trainer was used at all. The FDA never contacted the Epi-No company to ascertain whether the device in question was infact a product of the Epi-no company. Fake Epi-Nos have been manufactured in China and it would have taken a minimum of effort before publishing this report on the website to check the Lot number written on the box, if there was indeed a box, to see if this Epi-No was made by Tecsana. The Epi-no device itself is not marked in anyway to identify its name or manufacturer. This lack of thoroughness is enough to discount the adverse event report. Before establishing that the device in question was made by Tecsana, the FDA is pushing legal limits by publishing such a report about the Tecsana Epi-No on their website.

In addition, the only evidence that an Epi-No was used at all was reported by the male partner. The woman's version of the facts is completely missing from all reports, even though she spent 10 days in the hospital, most of it conscious and fully responsive. This adds suspicion to the accuracy of the adverse event report.

In addition, Dr Linda M. Nicoll carefully reports that the male partner attempted to inflate the Epi-No for 10 to 20 minutes inside his partner's vagina without being able to inflate the balloon. She submitted the following for publication in OBGYN: "The patient's husband was having some difficulty inflating the device and found that it was not adequately maintaining pressure, so he continued to attempt to inflate the device. After ten to twenty minutes of attempted insufflation, the patient began to complain of vaginal pain and dizziness." This statement removes all logic from the adverse event report. The person who removed FDA approval based on this report has neglected think about the physics of balloons. Epino is a simple 3 inch balloon. The instructions clearly say to check whether the balloon has a hole before inserting in the vagina. These instructions were ignored by both members of the couple. In the case of blowing up a 3 inch balloon the instructions are obvious. Anyone who has blown up balloons knows that if the balloon does not inflate, it has a hole in it. Anyone who has ever inflated a 3 inch balloon knows that if a balloon does not inflate in less than 10 seconds (not minutes), that it has a hole. When the adult male reported to the doctors that he tried to inflate a 3 inch balloon for 10 to 20 minutes with no success, there is something terribly wrong with the story. There is no end to the scenarios one can conjure up that would end in a pregnant woman on the floor, semi-responsive, with aspirated vomit and incontinent of feces and urine. A man trying unsuccessfully to blow up a balloon with a hole in it for 10 to 20 minutes in his partner's vagina, for the purposes of stretching the perineum to prevent tearing at birth is perhaps the least likely.

Additional Problems with the Adverse Event report on the website:

The case report submitted for publication in OBGYN by Dr Linda M. Nicoll and Dr Daniel W. Skupski (March 07) states the father reported attempting to inflate the balloon for "10 to 20 minutes." The website adverse event report says "5 minutes".

The case report submitted for publication by 2 doctors states that, She "presented to the emergency room via ambulance after appearing to have had a seizure at home." "Following convulsive activity, the patient appeared minimally responsive." "Emergency medical services arrived in response to a 911 call and found the patient minimally responsive and vomiting." The adverse event report does not concur with this but rather says "EMS found her non-responsive".

The case report submitted for publication by 2 doctors states, "On presentation to the ER her heart rate was in the 130's, systolic blood pressures in the 90's and diastolic in the 50s. Her oxygen saturation was 98% while intubated and receiving

100% oxygen. The adverse event report states to "the patient had hypoxemia incompatible with life."

The case report submitted for publication by 2 doctors states, "the fetal heart was approximately 100 beats per minute." The website adverse event report states that the baby had "bradycardia". Technically below 110 is bradycardia, but 100 might be expected in a fetus that had lots of IV Valium on board. "Fetal heart of 100 beats per minute, under the influence of IV Valium" would be exquisitely accurate. Bradycardia is a vague, inadequate description of the fetal heart on admission.

The website adverse event report states, "We believe her diagnosis was air embolus, caused by use of the epi-no device." It does not define who the "We" are. If an air embolism was the cause, how an air embolism entered the venus circulation was not even suggested. Was there an open vaginal gash? There was no bleeding reported. How did air enter into the venous circulatory system, with membranes intact and almost no cervical dilation? How does 1.5 inches of a balloon, near the entrance to her vagina caused air embolism?
The case report submitted for publication by 2 doctors states, "other etiologies for the serious medical complications suffered by the above patient are possible" "it is possible that the acute lung injury she suffered was due to aspiration of gastric contents alone, as opposed to embolic insult"
She may have suffered from a seizure, vasal vagal response to pain, or stroke. No attempt was made to rule out drug abuse. Another possible scenario is she held a plastic bag over her head for 5 minutes.

The website adverse event report states, "The ems driver said that the husband told him that the gauge indicated that the device was not holding pressure, so he used the bulb to reinflate the device." This statement is meaningless. The bulb is the only way to inflate the device. Gauges never hold pressure- they measure pressure. Was this statement made to cover up the truth with statements that sound superficially intelligent and hope that no one actually thinks about what is being said.

Unapproved use of device

If an air embolism was caused by an man attempting to inflate a balloon with a hole in it for "10 to 20 minutes", inside his partner's vagina- this would not be a "fault" of the Epi-No, but rather the fault of the man and perhaps the female partner, for using the device in a womans orifice in an unapproved fashion. Again, it is seriously suspicious that the entire medical history was taken only by the male partner, and the woman's story is completely absent from the story. Such a silence is unexpected on the part of this pregnant woman who supposedly is intelligent and educated enough to want to prevent perineal damage at the time of birth by buying and using an Epi-No.

Many devices, if not all devices with FDA approval, can be used in non-approved ways to do damage, even kill. If the FDA held up all devices to a level of scrutiny that the device could not cause damage if a user uses it in an unapproved way- there would not be a single device nor a single drug that would get FDA approval.

Epi-No has the ability to save womens lives

In addition to the lack of evidence that Epi-No, when used correctly has ever had any serious adverse events, Epi-No has the potential to save lives and may have already.

There is no question that for the past century, the direction of birth has been one in which the woman is more and more a patient who is laid down and treated, rather than one who actively accomplishes a physiologic function of her body. EPINO is a device which helps women regain some of the confidence to accomplish that physiologic function which is part of her capabilities.

The removal of FDA approval for a device which increase womens capability of physiologic birth, on the basis of an adverse event report which has either nothing to do with Epi-No or is a result of misuse of the device is in itself a potentially life threatening action on the part of the FDA. It has been proven by serious medical research that physiologic birth has a lower infant and maternal mortality rates for low risk women than interventive birth. Therefore devices such as Epi-No which increase womens ability for physiological birth are not just psychological placebos. Epi-No can save lives by avoiding unnecessary cesareans, vacuum birth and episiotomies and facilitating VBACs. There are cases in the literature of women who died from infections from episiotomy and 1/10,000 women die from cesareans. Epi-No deserves FDA approval not because it is a flaky way for women to feel empowered but rather because it has the potential to save womens lives by promoting vaginal birth.

There is no evidence presented in the adverse event report that Epi-No was a cause of a life-threatening adverse reaction. Either this adverse reaction had nothing to do with the use of Epi-No made by Tecsana, or an Epi-No at all, or the adverse reaction was due to the weird use of an Epi-No birth trainer used by some method defying any and all logic.

Looking forward to hearing from you.

Sincerely
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